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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,056	11/13/2001	Mark Henry Pausch	01142.0101	6857

7590 04/22/2003

Finnegan Henderson Farabow
Garrett & Dunner
1300 I Street NW
Washington, DC 20005-3315

EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/22/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,056

Applicant(s)

PAUSCH ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13,26 and 52-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 13,26 and 52-85 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Office Action

Restriction Requirement:

Applicants election of Invention II, now represented by claims 13, 26 and 52-85, in Paper number 12, filed 2/7/03, is acknowledged.

Applicants newly filed claims are drawn to several patentably distinct inventions. Thus, further restriction *within* the formerly presented Invention II is required, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 13, 60, 61, 62, 63, 64, 81 and 84, drawn to a method of screening compounds that bind to a heterologous, constitutively-active G-protein coupled receptor, by measuring cell growth.
- II. Claims 26, 52, 53 and 54, drawn to a method of screening compounds that bind to a heterologous G-protein coupled receptor, by measuring cell growth in a host cell comprising a mutation in a kinase that results in improved functional response of the G-protein coupled receptor.
- III. Claim 55, drawn to a method of screening compounds that bind to a heterologous G-protein coupled receptor, by measuring cell growth in a host cell comprising a mutated gene that

encodes a component of the endocytic or degradative pathway.

IV. Claims 56 and 57, drawn to a method of screening compounds that bind to a heterologous G-protein coupled receptor, by measuring cell growth in a host cell comprising a mutated gene that encodes a sterol isomerase.

V. Claim 58, drawn to a method of screening compounds that bind to a heterologous G-protein coupled receptor (pick one), by measuring cell growth in a host cell comprising a mutated gene that encodes ERG6.

VI. Claim 59, drawn to a method of screening compounds that bind to a heterologous G-protein coupled receptor (pick one), by measuring cell growth in a host cell comprising a mutated gene that allows the host cell to grow in the presence of exogenously added sterols.

VII. Claims 65 and 66, drawn to a method of screening compounds that bind to a heterologous, constitutively-active, human alpha adrenergic receptor with modifications in the third intracellular loop.

VIII. Claims 67-69, drawn to a method of screening compounds that bind to a heterologous, constitutively-active, M3 muscarinic acetylcholine receptor with modifications in one residue.

IX. Claims 70-80, 82, 83 and 85, drawn to a method of screening compounds that bind to a G-protein coupled receptor in a host cell comprising a chimeric G-protein alpha subunit gene (pick one heterologous G-protein coupled receptor).

The inventions are distinct, each from the other because of the following reasons:

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Inventions I-IX are independent and distinct, each from the other, because they comprise and use products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The methods of Inventions I-IX can be used each independently to study: constitutive activation of a G-protein coupled receptor; effect of a mutation in a kinase on cellular response; G-protein coupled receptor degradation or inactivating sequestration; effect of a mutation in a sterol isomerase on cellular response; effect of mutations in an alpha adrenergic receptor on cellular response; or, the effects of modifications of the G-protein alpha subunit.

Furthermore, the methods of Inventions I-IX are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials (cells, heterologous receptors, mutations, and enzymes), process steps (transfection steps and measuring steps), and goals (testing the effect of a particular enzyme, mutation, etc.).

Restriction

Furthermore, for Inventions V and IX applicant is required to elect one heterologous G-protein coupled receptor from the following:

- a) human melanocortin receptor (note: a specific receptor will need to be identified),

- b) rat somatostatin SSTR2 receptor,
- c) rat M3 muscarinic acetylcholine receptor,
- d) a rat CCK-B receptor,
- e) a rat adenosine A2a [receptor],
- f) a rat muscarinic M2 receptor,
- g) a *D. melanogaster* muscarinic acetylcholine M1 [receptor],
- h) a rat neurotensin NT-1 [receptor],
- i) human vasopressin V2 [receptor],
- j) a rat CCK-A [receptor],
- k) a human GnRh [receptor],
- l) a human melanocortin MCR4 [receptor],
- m) a human α 2A adrenergic [receptor],
- n) an *Aplysia* octopamine OA1 [receptor],
- p) a human bombesin BRS3 [receptor] and bombesin receptor related sequence 3,
- q) a human histamine H3 [receptor], or
- r) a human β 2-adrenergic [receptor].

Furthermore, each receptor represents a patentably distinct invention.

Groups (a) through (r) are independent and distinct, each from the other, because

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they have different putative functions, different structures, and require completely different search terms, starting points and strategies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be

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reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

April 21, 2003


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600